

INFORMATION DISCLOSURE CITATION

Form PTO-1449 (Modified) (Use several sheets if necessary)

ATTY. DOCKET NO. UCSF129CIP	SERIAL NO. 09/817,360
APPLICANT GERMAN et al.	CONFIRMATION NO. 2345
FILING DATE MARCH 20, 2001	EXAMINER (GROUP) UNASSIGNED (1635)

JUL 0 2 2001 **U.S. PATENT DOCUMENTS** & ZBADEMAR Examiner Document Date Name Class Subclass Filing Date Initial Number If Appropriate 5,795,723 08/18/98 AA Tapscott et al BU AB 5,830,730 11/03/98 German et al. BA AC 10/03/00 6,127,598 German et al. FOREIGN PATENT DOCUMENTS Document Date Country Class Subclass Translation Number Yes No AD WO 01/01130 04 JAN 2001 PCT WIFO \mathcal{B} ~ OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.) GenBank Accession No. U76208, deposited February 5, 1997 GenBank Accession No. Y09167, deposited November 14, 1997. GenBank Accession No. Y10619, deposited May 6, 1997. AH' GenBank Accession No. AJ133776.1, deposited June 19, 1999. GenBank Accession No. NM_020999, deposited November 29, 2000. ΑI Furuta et al. (August 1998), "Beta-Cell Transcription Factors and Diabetes." Diabetes, Vol. 47:1356-1358. AJGoldfine et al. (December 1997), "The Endocrine Secretion of Human Insulin and Growth Hormone by AK Exocrine Glands of the Gastrointestinal Tract." Nature Biotechnology, Vol. 15:1378-1382. Horikawa et al. (November 2000), "Beta-Cell Transcription Factors and Diabetes." Diabetes, Vol. 49:1955-AL1957.

EXAMINER O	DATE CONSIDERED
Ship materia	
EXAMINER : Initial if reference considered, whether	or not citation is in conformance with MPEP 609; Draw line through
citation if	•
not in conformance and not considered. Include copy	of this form with next communication to applicant.

Expression and Linkage Mapping of Chromosome 9." Genomics, Vol. 43:520-524.

(NKX6A), a New Pancreatic Islet Homeobox Gene." Genomics, Vol. 40:367-370.

Iannotti et al. (1997), "Identification of a Human LMX1 (LMX1.1)-Related Gene, LMX1.2: Tissue Specific

Inoue et al. (1997), "Isolation, Characterization, and Chromosomal Mapping of the Human Nkx6.1 Gene

INFORMATION DISCLOSURE CITATION

(Use serval sheets if necessary)

ATTY. DOCKET NO. UCSF129CIP	SERIAL NO. 09/817,360
APPLICANT GERMAN et al.	CONFIRMATION NO. 2345
FILING DATE MARCH 20, 2001	EXAMINER (GROUP) UNASSIGNED (1635)

	W.	, cr ^k
۲,	>	MATTITA et al. (May 12, 2000), "Beta-Cell Differentiation Factor Nkx6.1 Contains Distinct DNA Binding Interference and Transcriptional Repression Domains." <i>The Journal of Biochemistry</i> , Vol. 275(19):14743-14751.
	AP	Odagiri et al. (January 26, 1996), "Function of the Human Insulin Promoter in Primary Cultured Islet Cells." <i>The Journal of Biochemistry</i> , Vol. 271(4):1909-1915.
	AQ	Ogata et al. (March 2001), "Mutations in the Coding Region of Neurogenin 3 Gene (NEUROG3) are no Common Cause of Maturity-Onset Diabetes in Japanese Subject." <i>Diabetes</i> , Vol. 50(3):694-696.
	AR	Rudnick et al. (December 1994), "Pancreatic Beta Cells Express a Diverse Set of Homeobox Genes." <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 91:12203-12207.
	AS	Sander et al. (September 1998), "A Novel Glucose-Responsive Element in the Human Insulin Gene Function as Uniquely in Primary Cultured Islets." <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 95:11572-11577.
	AT	Sander et al. (1997), "The beta Cell Transcription Factors and Development of the Pancreas." <i>J. Mol. Med.</i> , Vol. 75:327-340.
	AU "	Sander et al. (1997), "Genetic Analysis Reveals that PAX6 is Required for Normal Transcription of Pancreatic Hormone Genes and Islet Development." <i>Genes and Development</i> , Vol. 11:1662-1673.
	AV	Sander et al. (2000), "Homeobox Gene Nkx6.1 Lies Downstream of Nkx2.2 in the Major Pathway of Beta-Cell Formation in the Pancreas." <i>Development</i> , Vol. 127:5533-5540.
D~	AW	Schwizgebel et al. (2000), "Expression of Neurogenenin3 Reveals an Islet Cell Precursor Population in the Pancreas." <i>Development</i> , Vol. 127:3533-3542.
	AX	Sommer et al. (1996, "Neurogenins, a Novel Family of Atonal-Related bHLH Transcription Factors, Are Putative Mammalian Neuronal Determination Genes that Reveal Progenitor Cell Heterogeneity in the Developing CNS and PNS." Molecular and Cellular Neuroscience, Vol. 8:221-241.
Dv.	AY	Sussel et al. (1998), "Mice Lacking the Homeodomain Transcription Factor Kkx2.2 Have Diabetes due to Arrested Differentiation of Pancreatic Beta Cells." <i>Development</i> , Vol. 125:2213-2221.
	AZ	Wang et al. (April 1997), "Regulation of Insulin preRNA Splicing by Glucose." <i>Proc. Natl. Acad. Sci. USA.</i> , Vol. 94:4360-4365.
BN.	BA	Watada et al. (2000), "Transcriptional and Translational Regulation of Beta-Cell Differentiation Factor Nkx6.1." <i>The Journal of Biological Chemistry</i> , Vol. 275(44):34224-34230.

EXAMINER BAR A LATER DATE CONSIDERED 1/02

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if

not in conformance and not considered. Include copy of this form with next communication to applicant.



#6

PTO/SB/08A (08-00) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Inder the Raperwes Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 1					т	Application Nu Filing Date First Named In Group Art Unit Examiner Nam Attorney Docke	mber ventor	09/81 Marcl GERM 1647 UNAS	if Known 7,360 h 20, 2001 MAN, MICHAEL S. T \{ 2 \} SSIGNED F-129CIP	TECH CENTER 16	APR 1 6 20
										g	
					U.S. F	PATENT DOCU	MENTS			<u> 22</u>	
Examiner Initials'	Cite No. ¹	U.S. Pat Number	ent Docum Kind (if knowr	Code ²		etentee or Applicant ad Documents	Date of Public of Cited Docum MM-DD-YY	ment	Pages, colu Where F Passages c Figures	mns, lines Relevant or Relevant	

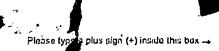
	FOREIGN PATENT DOCUMENTS								
Examiner Initials'	Cite No.1	Foreign Patent Documents Office ³ Number ⁴ Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т°			
DV		WO 98/13491	ANDERSON ET AL.	APRIL 2, 1998					
DV		WO 00/09676	ANDERSON ET AL.	FEBRUARY 24, 2000					

21/02
11111

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard St.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.



#7

PTO/58/08A (08-00)
Approved for use through 10/31/2002, OMB 0651-0031
U.S. Palent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are regulared to respond to a collection of information unless it contains a valid OMB control number.

Substitute	for form 1449A/PTO					Complete if Known	COPY OF PAP	
Copania	igradiii (Visiti io				Application Number	09/817,360	ORIGINALLY P	LED
	INFORMATION DISC	CLOS	URE		Filing Date	March 20, 2001	9/01/02	58
	STATEMENT BY APPLICANT				First Named Inventor	German, et al.	7	
					Group Art Unit	1635		
	(uso as many sheets as	necessa	ary)		Examiner Name	Unassigned		
Shoot	1	of	1	2	Attorney Docket Number	UCSF-129CIP		ļ

	U.S. PATENT DOCUMENTS							
Examin er initials'	Cile No. ¹	U.S. Patent Documents Number Kind Code ² (if known)	Name of Patentce or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pagas, columns, lines, Where Relovant Passages or Relevant Figures Appoar			
OW	AA	5,795,723	Tapscott, et al.	08-18-1998				

	FOREIGN PATENT DOCUMENTS									
Examiner Initials'	Cile No.'	Foreign Palant Documents Office ³ Number ⁴ Kind Code ⁵ (<i>Il known</i>)	Name of Patentee or Applicant of Ciled Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passagos or Relevant Figures Appoar	T ⁶				
B~	AB	WO 96/34093	Lee, et al.	10-31-1996						

		OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Initials* item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
p.	AC /	GRADWOHL, et al. "Neurogenin3 is required for the development of the four endocrine cell lineages of the pancreas", <i>Proc. Natl. Acad. Sci. USA.</i> , (2000) Vol. 97(4): 1607-1611.		
	AD	HUANG, et al. "Transcription factors involved in pancreatic islet development", J. Biomedical Sci., (2000) Vol. 7(1): 27-34.		
	AE	JENSEN, et al. "Independent development of pancreatic alpha and beta cells from neurogenin3 – expressing precursors: A role for the Notch pathway in repression of premature differentiation", <i>Diabetes</i> , (2000) Vol. 49(2): 163-176.		
	AF	RAVASSARD, et al. "Relax, a novel rat bHLH transcriptional regulator transiently expressed in the ventricular proliferating zone of the developing central nervous system", Canadian J. Chem., (1997) Vol. 48(2): 146-158.		
	AG	RAVASSARD, et al. 'Homo sapiens gene for neurogenin3'', Database EMBL Online, (1999) Database accession No. AJ33776.		
12 ×	AH	RUDINGER. "Characteristics of the amino acids as components of a peptide hormone sequence" in <i>Peptide Hormones</i> (ed. J.A. Parson), (1976) pp. 1-7, University Park Press, Baltimore.		

Examiner D. A. A.	Date (1)/71/60
Signature // Signature	the ALDED SOO. Day, they though distingtiff not be conformance and not

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the Individual case. Any comments on the amount of time you are regulated to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Officer, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

BOZICEVIC, FIELD&FRANCIS



Please type a plus sign (+) inside this bux ->

PTO/SB/08A (08-00) Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO			•	Complete if Known		
			•	Application Number	09/817,360	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (yes as many shorts as necessary)				Filing Date	March 20, 2001	
				First Named Inventor	German, et al.	
				Group Art Unit	1635	
				Examiner Name	Unassigned	
Sheet	7 1989 No Interior	of	2	Altorney Docket Number	UCSF-129CIP	

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), tills of the article (when appropriate), tills of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²				
DV	Al	SOMMER, et al., "Neurogenins, a novel family of atonal-related bHLH transcription factors, are putative mammalian neuronal determination genes that reveal progenitor cell heterogeneity in the developing CNS and PNS," Molecular and Cellular Neuroscience, (1996) Vol. 8: 221-241.					
	AJ	GenBank Accession No. U76208, deposited Feb. 5, 1997					
	AK	GenBank Accession No. Y09167, deposited Nov. 14, 1997	 -				
שת	AL	GenBank Accession No. Y10619, deposited May 6, 1997	1				

Examiner Signature Signature	Date Considered ()/2/07	
Signature 1 / /////		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Unique citation designation number. Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.